ADAP ADVISORY COMMITTEE MEETING
SEPTEMBER 18, 2007
HENRICO DOCTORS HOSPITAL

Members Present: Linda Eastham RN FNP, George Kelly, Craig Parrish RPh, Daniel Nixon DO, Peg Tipple MD, Donald Walker, and David Wheeler MD.

VDH Staff: Diana Jordan RN MS, Steve Bailey LCSW, Faye Bates RN BSN, and David Ciucci.

Other: Anne Rhodes, Kevin Jackson, and Larry Winfield.

The meeting was called to order at 10:15 a.m. by Diana Jordan, Director of Health Care Services. Introductions were made. There were visitors present and ground rules were presented. Guests are welcome to this public meeting as observers and were asked to refrain from commenting unless asked a question by a member or VDH staff person. The minutes from the April 17, 2007 meeting were reviewed and approved as written.

Diana Jordan offered an update on testing. VDH applied for a CDC funding opportunity entitled, "Expanded and Integrated HIV Testing for Populations Disproportionately Affected by HIV, Primarily African Americans." Official notification of receipt of funding is pending, and prospects for funding look promising. An update will be provided when available. If funded, Virginia will expand testing to a variety of settings including select community health clinics, emergency rooms, and jails. An update will be provided at the next meeting.

VDH has issued guidance on CDC's Revised HIV Testing Recommendations in Health-Care Setting vs. Virginia Code, which is available on the VDH website and included in the meeting packet.
http://www.vdh.virgina.gov/epidemiology/DiseasePrevention/documents/HIVscreeningandVirginialaw.doc.
Several ADAP Advisory Committee members assisted by reviewing the document prior to release. Diana Jordan thanked those who contributed.

Steve Bailey reported that SPAP is progressing well. The contractor, Patient Services Incorporated (PSI) continues to enroll clients for premium assistance. Due to funding shortfalls, less than 40 clients will receive full medication support. Other clients will be placed on a wait list based upon the date of enrollment. PSI is in the process of a data exchange testing phase with the Centers for Medicare and Medicaid Services (CMS). When testing is completed, PSI will start implementing cost sharing. Medicare Part D open enrollment starts in November. There will be educational activities planned to assist clients on plan selection.

Diana Jordan reported a significant funding update. VDH received a MAI award of $203,896 which represents a 91% increase from last year. HRSA has mandated Part B MAI funds be used to link individuals to ADAP services. VDH is increasing funds to existing contractors in the Northern and Eastern regions and will support a new service provider through VCU in the south central region of the state. VDH will blend funding using base dollars for agreements so that providers can also link individuals to primary medical care and other services.

VDH received a substantial ADAP Supplemental Award of $4,045,526. Only $746,636 was received in supplemental funding last year. While this is very good news, it does present a challenge to identify enough matching funds for a very large unanticipated amount. This brings the total federal funding for ADAP just under $20.8 million. The overall award exceeds $28.9 million. Reauthorization requires the spending of supplemental funding first and establishes penalties for carryover exceeding 2% of the total Ryan White Award. Strategies will include:

- Continuing to add medications to the ADAP formulary,
- Investigating a centralized eligibility process to relieve some burden from local health departments and to improve compliance with HRSA requirements related to completing eligibilities every 6 months. VDH is currently researching and receiving technical assistance for this project. Steve Bailey will be visiting Texas next week to research an exciting state level eligibility system and see what can be incorporated into development of our own.
- Develop a sole source agreement that will allow ADAP to pay for CCR5 tropism testing.
- Examine current eligibility criteria to see if there should be an increase in the federal poverty level (FPL) income limit.

Donald Walker asked if restrictions will be removed from certain medications since additional funding is available. Dr. Nixon responded that a second generation PI, such as darunavir, is generally indicated for second line therapy. Before drugs are approved for first line therapy, hard clinical data must support usage for initial therapy. Darunavir and raltegravir once daily regimens are presently being studied.

Diana Jordan informed the Committee that the recently approved medication, maraviroc (Selzentry) requires a CCR5 tropism test. The blood test, known as Trofile, is the phenotypic test that is Clinical Laboratory Improvement Amendments (CLIA) validated, and the only tropism test used in the clinical trials. Only one company, Monogram Biosciences, provides this assay. The cost of the test for tropism is approximately $1560. The National Alliance of State and Territorial AIDS Directors (NASTAD) ADAP Crisis Task Force has come to an agreement with Pfizer on the pricing of maraviroc.

ADAP financial eligibility criteria is being examined. Health Care Services staff is working with the Health and Research Informatics (HRI) Unit, looking at projections in regard to the federal poverty level (FPL) eligibility limits. This will look at the possibility of providing services to clients with higher income levels. Formulary additions will be made to expand statewide access to medications.

Faye Bates initiated a discussion on additions to the ADAP formulary. There are several medications for consideration for the antilipidemic class. There was a request from the April 17, 2007 ADAP Advisory Committee meeting to consider rosuvastatin (Crestor) and omega-3 acid ethyl ester (fish oil, Omacor) for formulary addition. Discussion took place regarding the medications. It was mentioned that rosuvastatin works well with protease inhibitors (PIs). Fish oil is available over the counter (OTC) and less cost effective even at ADAP pricing. After much discussion, the Committee unanimously agreed to add rosuvastatin to the formulary. There was a vote on the addition of the fish oil. Vote results dictated not to add the medication at this time and reevaluate the addition at a future meeting. Dr. Tipple suggested reviewing the utilization of the existing antilipidemics on the formulary and look at trends with HIV client population in relation to cardiovascular disease and diabetes.

The next medication for formulary consideration is an addition to the antihyperglycemic agents. A request was made at the April 17, 2007 Advisory Committee meeting to consider rosiglitazone (Avandia) and pioglitazone (Actos) for addition. Medication utilization was hard to predict at this time and it would be at the discretion of the prescriber. It was also mentioned that the FDA had issued a press release on rosiglatizone and cardiac disease. Medication is to be used with caution with clients with history of cardiac disease. There was a similar warning regarding pioglitazone. Voting was unanimous to not add these diabetes medications. It was mentioned that these two medications do not prevent the need for insulin use at a later time.

The next class of drugs for formulary addition is psychotropics. Medications for consideration are amitriptyline, bupropion, citalopram, doxepin, duloxetine, escitalopram, fluoxetine, mirtazapine, nortriptyline, paroxetine, sertraline, trazodone, venlafaxine, buspirone, hydroxyzine, lithium, chlorpromazine, haloperidol, olanzapine, risperidone, and ziprasidone. These medications are currently on the Part B Non-ADAP formulary, and are often purchased through retail pharmacies. ADAP has the ability to purchase these medications at reduced prices. Utilization and cost was hard to determine due to prescriber preference. Clients could be on a combination of medications mentioned above at any given time. Committee members suggested seeking an expert in the mental health field such as a psychiatrist who has worked with HIV patients, to provide input on use, indications, and issues related to HIV disease and treatment. Committee members noted having limited knowledge about psychiatric treatment. This led to discussion about whether the ADAP Advisory Committee is going outside of the scope of its mission. Discussion reinforced that ADAP should be for the purpose of medication distribution to eligible clients. The medication addition for mental health drugs was put to a vote. The options were to hold the list for future consideration and obtain additional information, or add the medications and obtain additional information from a psychiatrist or other trained mental health expert. The vote was unanimous to add the medications and obtain additional information on the medications from a mental health expert. Diana Jordan will obtain input from the HRSA Project Officer on the medication classification and input will be sought from a psychiatric medical provider.

A possible agenda item for the next meeting is to have an experienced clinician address the Advisory Committee members on the mental health medications. A second agenda item is to discuss the overall mission of the ADAP Advisory Committee.

Faye Bates initiated a discussion on the new recently FDA approved medication for HIV treatment. Maraviroc (Selzentry) is a new class of medication, co-receptor antagonist. The indication for usage, according to the package insert, is for use in combination with other antiretroviral agents, and is indicated for treatment experienced adult patients infected with only CCR5-tropic HIV-1, who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents. This medication requires a blood test for the CCR5 co-receptor. This medication is effective only for individuals who test positive. Maraviroc is an option when other treatment regimens are not effective. Ryan White Reauthorization mandates new drug classes in the treatment of HIV/AIDS must be added to the state ADAP formularies.

Utilization on the request for the test is estimated at 200 in Virginia. The estimated cost of the tropism test is $1560. The question for discussion is how the test will be paid for and should ADAP funds be used to pay for tests. Much discussion took place regarding this topic with the Committee preferring to not pay for the diagnostic test with ADAP funds. There was a concern that ADAP should remain a pharmaceutical program. Committee suggested investigating another payment source for testing.

Exception criteria for the tropism test and maraviroc was presented for discussion. Since this medication is indicated for the treatment experienced client, the question for discussion was asked if the present criteria for enfuvirtide, darunavir, and tipranavir is suitable for maraviroc. The committee decided that the exception criteria for tropism testing will be NRTI and NNRTI experienced or contraindicated with a viral load greater than 1000 and prior experience with 1 or more PIs.

It was also decided that the criteria for maraviroc is NRTI and NNRTI experienced or contraindicated and prior experience with 1 or more PIs with a positive blood test for the CCR5 co-receptor within 3 months. Any clients who have participated in a maraviroc clinical trial or an expanded access program will be eligible to receive maraviroc. Clinicians will need to indicate study participation under, “Reason for Exception” on the ADAP Medication Exception Form. A request was made to revisit the exception criteria for darunavir at the next meeting.

Faye Bates conducted a slide presentation on the Seamless Transition Program for the calendar year 2006. There were 84 Seamless Transition referrals in 2007. Forty six post release inmates failed initial appointments within two months of release. A breakdown of appointment failure was broken down by regions. Comparisons of 2005 and 2006 rates were presented. Faye Bates briefly discussed an initiative in one of the regions that provides care coordination for individuals within 6 months of being released and living with HIV or AIDS. An interesting finding revealed that 16 of the 46 post release inmates did enroll in ADAP two or more months after initial referral. Nine of these individuals enrolled at a different health department than originally referred. This reduced the

overall failure rate for 2006 to 36%. Challenges for the program are getting into care, and getting into care sooner. Questions were raised as to how many of the inmates were women, how many were men, and the facilities with the highest rate of inmate noncompliance. This information was requested to be an agenda item for the next meeting. There was a suggestion that contact information be given to released inmates, such as the toll free hotline number to help them remember where and how to obtain their medications.

Anne Rhodes from Survey Evaluation and Research Laboratory (SERL) gave a brief overview of the Criminal Justice Drug Abuse Study. This project involves the coordination of care at prisons, jails, and community corrections. Virginia Department of Corrections is a partner with this project. If funding is approved, there will be a pilot program in Central Virginia using peer advocates prior to release to be involved in pre-release planning. Linking clients to services is vital to this project. Activities consist of focus groups to find newly released inmates to determine why they did not get into care. This project could be used to strengthen the Seamless Transition Program to increase compliance.

Anne Rhodes presented the Virginia ADAP Data Report for September 2007. The total number of clients served July 2006 to June 2007 is 3191. Overall, the length of time on ADAP is increasing from 43 months in 03-04 to 48 months in 06-07. A chart with a comparison of national ADAP data prepared by NASTAD was presented. Both sources showed that males are the highest percentage of clients who access ADAP. Drug utilization showed that NRTIs are the highest prescribed antiretrovirals (above 30%). African Americans and Hispanics are the majority of new clients enrolled.

A data request was made to determine why boosted PI usage is decreasing and to include regional prescribing patterns. The data results may present an opportunity for continuing education for clinicians.

A suggestion was made that dates and times be set for future meetings. It was suggested that the next meeting be scheduled for December or January. Faye Bates will select a date and notify committee members. For the next meeting, an update on the Incidence and Resistance data was requested, and an agenda sent prior to the meeting was requested.

The meeting was adjourned at 2:15 p.m.